

REMARKS

With the entry of this Response, Claims 85-110 and 112 are pending. Claims 1-84 and 111 have been previously canceled. Applicant has amended Claims 85-86, 88-89, 91-95, 97, 99-107, 109-110, and 112.

Support for the amendments to the claims can be found at least in the claims as filed and in paragraphs [0069], [0070], [0071], [0077], [0078], [0083], FIG. 2, and FIG. 4 of Applicant's published patent application. No new matter is believed to be added by these amendments.

Claims 85, 94, and 103 are independent claims. Claims 86-93 depend from Claim 85. Claims 95-102 depend from Claim 94. Claims 104-110 and 112 depend from Claim 103. In view of the subsequent remarks regarding these independent claims, Applicant respectfully requests allowance of all the pending claims.

35 U.S.C. § 103(a) REJECTION

A. Claims 85-93

The Office Action rejected Claims 85-93 under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,920,396 issued to Wallace *et al.* ("Wallace") in view of U.S. Patent Application Publication No. 2003/0118599 to Algate *et al.* ("Algaté"). Applicant respectfully traverses this rejection to the extent that it applies to the claims as amended.

Applicant's currently pending independent Claim 85 recites, in part, "receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data."

Under 35 U.S.C. § 103(a), the Patent Office bears the burden of establishing a *prima facie* case of obviousness. A *prima facie* case of obviousness requires: (1) that there be a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of reference or to combine the teachings of multiple references; (2) that there be a reasonable expectation of success; and (3) that the prior art reference, or references when combined, teach or suggest all of the elements of the claim. (*See, e.g., M.P.E.P. § 2143*). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on Applicant's disclosure. (*See, e.g., In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991); In re Fine, 87 F.2d 1071, 1074 (Fed. Cir. 1988)*). Furthermore, rejections based on obviousness

grounds cannot be sustained by mere conclusory statements; instead, there must be explicit analysis including some rational underpinning to support the legal conclusion of obviousness. (*K.S.R. Int'l Co. v. Teleflex, Inc.*, 550 U.S. 14 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). If the references do not teach each and every claimed element, then a finding of obviousness fails.

Applicant respectfully submits that the combination of Wallace and Algaté fail to teach or suggest each and every element of currently pending independent Claim 85. By citing Algaté for disclosing that “the results comprise at least comprise at least immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data ([0723] and [0809]),” the Office Action appears to have conceded that Wallace fails to teach or suggest “*receiving from the plurality of databases query result data comprising immunohistological data, in situ hybridization data, functional data, expression data, and structural data*” as currently recited in Applicant’s independent Claim 85. Applicant respectfully submits that Algaté, which is generally directed to compositions and methods for the therapy and diagnosis of lung cancer, fails to cure the deficiencies of Wallace. In making this rejection, the Office Action cited paragraphs [0723] and [0809] in Algaté. Applicant notes that neither of these cited paragraphs, nor any other paragraph of Algaté, teaches or suggests “receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data” as currently claimed in step (c) of independent Claim 85.

For example, paragraph [0723] of Algaté explains that the disclosed polypeptides and portions thereof for the therapy and diagnosis of lung cancer can be immunogenic. In other words, Algaté explains that a portion of the immunogenic polypeptide can also be immunologically reactive in that it can bind to B-cell or T-cell surface antigen receptors that bind the polypeptide. However, Algaté says nothing about (1) query result data comprising immunohistological data, or (2) query result data comprising *in situ* hybridization data, or (3) query result data comprising functional data, or (4) query result data comprising expression data, or (5) query result data comprising structural data. Furthermore, Algaté says nothing about receiving from the plurality of databases query results that comprise all these types of data. Consequently, Applicant further submits that the skilled person would not equate the description of immunogenic portions of polypeptides provided in paragraph [0723] of Algaté with “receiving

from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data” as currently claimed.

Similarly, paragraph [0809] of Algate explains that the art is familiar with peptide nucleic acids or PNAs, and that the skilled person would be familiar with the use of PNAs in a variety of applications including DNA strand invasion, antisense inhibition, blocking of transcription factor binding, and *in situ* hybridization. In other words, Algate explains that PNAs have multiple uses. Although Algate identifies “*in situ* hybridization” as one of the applications for PNAs, Algate says nothing about (1) query result data comprising immunohistological data, or (2) query result data comprising *in situ* hybridization data, or (3) query result data comprising functional data, or (4) query result data comprising expression data, or (5) query result data comprising structural data. Furthermore, Algate says nothing about receiving from the plurality of databases query results that comprise all these types of data. Consequently, Applicant submits that the skilled person would not equate the description of PNAs provided in paragraph [0809] of Algate with “receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data” as currently claimed.

The failure of the combination of Wallace and Algate to teach each and every element of step (c) of Applicant’s currently pending independent Claim 85 is similarly repeated with respect to step (g) of Claim 85. Step (g) recites “displaying an executive summary of the record.” Applicant’s specification explains that the “various modules can be viewed in an executive summary” and that “an ‘executive summary’ is a summary of all the information associated with a record (unique identification record).” For example, “the executive summary displays the information found in the individual modules associated with the given record.” These modules include immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data. (See paragraphs [0070] and [0083] and FIG. 4). As the combination of Wallace and Algate fails to teach or suggest “receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data” as currently claimed, the combination of Wallace and Algate also necessarily fails to teach or suggest “displaying an executive summary of the record” as currently claimed.

In light of Wallace’s deficiencies and Algate’s failure to cure these deficiencies, the combination of Wallace and Algate fails to teach or suggest each and every element of

Applicant's currently pending independent Claim 85. Therefore, the combination fails to establish a *prima facie* case of obviousness.

Applicant also notes that it is the burden of the Office to provide a rationale from the asserted prior art for making the specific combination. The Supreme Court recently addressed nonobviousness of "combination" inventions in *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) (*KSR*). The Court confirmed that it is legally insufficient to merely point to the various recited elements. Instead, the Office must identify the basis for the alleged modification or combination by one of ordinary skill to arrive at the claimed invention.

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR at *37-*38 (emphasis by underlining added).

Furthermore, the Supreme Court opined that conclusory statements cannot provide an adequate basis for the alleged modification or combination; the reasoning must be explicit.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

KSR at *36-*37. Absent explicit reasoning to support the basis for the combination of references, the asserted combination cannot support a *prima facie* obviousness rejection.

Applicant has already discussed the failures of the combination of Wallace and Algate to teach or suggest each and every element of Applicant's currently pending Claim 85. Notwithstanding these failures, the Office Action stated with respect to Claim 85 "it would have been obvious to an ordinary person skilled in the art at the time of the invention was made to incorporate the teachings of Algate with the teachings of Wallace for the purpose of utilizing polypeptides and polynucleotides to produce pharmaceutical compositions, e.g., vaccines, and other compositions for the diagnosis and treatment of lung cancer ([0002] of Algate)." (Office Action, p. 5). Applicant is uncertain as to how the Office Action's statement relates to Applicant's currently pending Claim 85, which recites a method for managing a biological database. Applicant submits that the skilled person would clearly recognize that Algate is directed to compositions and methods for the therapy and diagnosis of lung cancer rather than to methods and systems for managing biological databases as currently claimed. Because Algate is entirely unrelated to Applicant's claimed method and because Algate fails to cure the deficiencies of Wallace, the Office Action has failed to provide explicit evidence of the motivation to combine Wallace and Algate to arrive at Applicant's currently claimed invention.

For at least these reasons, whether considered individually, or in combination with one another, the cited references fail to provide a teaching or suggestion that results in Applicant's currently claimed invention. Consequently, the combination of these references fails to render as obvious Applicant's currently pending independent Claim 85. Furthermore, as "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)), Applicant asserts that combination of Wallace and Algate also fails to render as obvious Claims 86-93, all of which depend from independent Claim 85 and incorporate every element of independent Claim 85. Applicant respectfully requests that the Examiner withdraw this rejection and allow these claims.

B. Claims 94-102

The Office Action rejected Claims 94-102 under 35 U.S.C. § 103(a) as obvious over Wallace in view of Algate, and further in view of U.S. Patent Application Publication No. 2003/0055683 to Gibson *et al.* ("Gibson"). Applicant respectfully traverses this rejection to the extent that it applies to the claims as amended.

Applicant's currently pending independent Claim 94 recites, in part, "receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data."

Applicant notes that the Office Action applied Wallace and Algaté in this § 103(a) rejection in the same way and for the same disclosure for which the Office Action applied these references in the § 103(a) rejection of Claim 85. In light of Wallace's deficiencies and Algaté's failure to cure these deficiencies, the combination of Wallace and Algaté also fails to teach or suggest each and every element of Applicant's currently pending independent Claim 94. Specifically, the combination of Wallace and Algaté fails to teach or suggest step (h), "receiving from the plurality of databases query result data comprising immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data," and step (l), "displaying an executive summary of the record."

Applicant notes that in the rejection of Claim 94, the Office Action also relied on Gibson for disclosing steps (a), (b), (c), (d), and (e). The Office Action stated that it would have been obvious to the skilled person to "incorporate the teaching of Gibson with the teachings of Wallace, as modified by Algaté, for the purpose of creating update drug data for addition to the original drug information, and a transmit mechanism that transmits the update drug data to the remote device upon receiving a request from a remote device for the update drug data." (Office Action, p. 12). Applicant is uncertain as to how the Office Action's statement relates to Applicant's claimed method of managing a biological database. The Office Action has failed to provide explicit evidence of motivation to combine Wallace with the compositions and methods for the therapy and diagnosis of lung cancer disclosed by Algaté and the methods and systems for disseminating drug information disclosed by Gibson. The skilled person simply would not look to the combination of Wallace, Algaté, and Gibson to arrive at Applicant's currently claimed invention.

For at least these reasons, whether considered individually, or in combination with one another, the combination of Wallace, Algaté, and Gibson fail to provide a teaching or suggestion that results in Applicant's currently claimed invention. Consequently, the combination of these references fails to render as obvious Applicant's currently pending independent Claim 94. Furthermore, as "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)),

Applicant asserts that combination of Wallace, Algatc, and Gibson also fails to render as obvious Claims 95-102, all of which depend from independent Claim 94 and incorporate every element of independent Claim 94. Applicant respectfully requests that the Examiner withdraw this rejection and allow these claims.

C. Claims 103-110 and 112

The Office Action rejected Claims 103-110 and 112 under 35 U.S.C. § 103(a) as obvious over Wallace in view of Algatc, and further in view of Gibson. Applicant respectfully traverses this rejection to the extent that it applies to the claims as amended.

Applicant's currently pending independent Claim 103 recites, in part, that "the first processor is configured to receive and store query result data in the biological database, wherein the biological database comprises a set of biological sequences and wherein the query result data comprises immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data, further wherein the target database node is configured to receive, from a user, a request to view a record of one of the set of biological sequences and display an executive summary of the record."

Applicant notes that the Office Action applied Wallace and Algatc in this § 103(a) rejection of Claim 103 in the same way and for the same disclosure for which the Office Action applied these references in the § 103(a) rejection of Claim 85 and Claim 94. In light of Wallace's deficiencies and Algatc's failure to cure these deficiencies, the combination of Wallace and Algatc fails to teach or suggest each and every element of Applicant's currently pending independent Claim 103. Specifically, the combination of Wallace and Algatc fails to teach or suggest (1) "wherein the query result data comprises immunohistological data, *in situ* hybridization data, functional data, expression data, and structural data," and (2) the "display of an executive summary of the record."

The Office Action stated that it would have been obvious to the skilled person to "incorporate the teaching of Gibson with the teachings of Wallace, as modified by Algatc, for the purpose of creating update drug data for addition to the original drug information, and a transmit mechanism that transmits the update drug data to the remote device upon receiving a request from a remote device for the update drug data." (Office Action, p. 12). Applicant is uncertain as to how the Office Action's statement relates to Applicant's claimed system for managing a

biological database. The Office Action has failed to provide explicit evidence of motivation to combine Wallace with the compositions and methods for the therapy and diagnosis of lung cancer disclosed by Algata and the methods and systems for disseminating drug information disclosed by Gibson. The skilled person simply would not look to the combination of Wallace, Algata, and Gibson to arrive at Applicant's currently claimed invention.

For at least these reasons, whether considered individually, or in combination with one another, the combination of Wallace, Algata, and Gibson fail to provide a teaching or suggestion that results in Applicant's currently claimed system. Consequently, the combination of these references fails to render as obvious Applicant's currently pending independent Claim 103. Furthermore, as "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (*In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988)), Applicant asserts that combination of Wallace, Algata, and Gibson also fails to render as obvious Claims 104-110 and 112, all of which depend from independent Claim 103 and incorporate every element of independent Claim 103. Applicant respectfully requests that the Examiner withdraw this rejection and allow these claims.

CONCLUSION

The foregoing is a complete response to the Office Action dated December 1, 2009. For at least the reasons provided above, Applicant respectfully requests allowance of all of the pending claims. Early and favorable consideration is solicited. If a telephone conversation would expedite the prosecution of these claims to issuance, then Applicant's representative invites and encourages the Examiner to contact the Applicant's representative at the telephone number listed below.

Applicant files this Amendment and Response solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicant does not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicant respectfully requests the Examiner to revisit any previously reviewed references cited in this

Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

With this Amendment and Response, Applicant also encloses a Petition for an Extension of Time to extend the time period for one-month, *i.e.*, to April 1, 2010, and a credit card payment in the amount of \$65, which represents the small entity fee pursuant to 37 C.F.R. § 1.17(a)(1). Applicant believes that this is the correct amount due; however, Applicant authorizes the Commissioner to charge to Deposit Account No. 14-0629 any additional fees that are required, or to credit to the same account any overpayment of fees.

Respectfully submitted,

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